A Conversation With Scott Gottlieb, MD

The impact of health care reform on access to biologics, health policy, and managed care.

Scott Gottlieb, MD, is one busy guy. One day he's putting the finishing touches on a policy paper for the American Enterprise Institute, the nonpartisan conservative think tank where he is a resident fellow. The next day he's testifying before Congress about Medicare costs. And the day after that, he's off to New York to fulfill his duty as an internist at NYU's Tisch Hospital. Then it's a red-eye to California for a meeting at Combimatrix, where he's on the board of directors, followed by a flight back to Washington, during which he's cranking out an op-ed piece for the *Wall Street Journal*.

Such is the life of a man who, at age 39, has achieved more than most people do in a lifetime. Since earning his MD at Mt. Sinai School of Medicine in 1999, Gottlieb has become a leading expert on health policy, regulation, and technology — due in part to his service in various capacities deep within our country's healthcare policymaking apparatus. From 2005 to 2007, he was deputy commissioner for Medical and Scientific Affairs at the U.S. Food and Drug Administration — the FDA's No. 2 job — and prior to that, he served as a senior policy adviser at the Centers for Medicare and Medicaid Services, where he was instrumental in the development of Medicare Part D. He also has had consulting roles with several biotech and pharmaceutical companies. Gottlieb is a charter member of the editorial board of BIOTECHNOLOGY HEALTHCARE.

Yet, for all his influence, Gottlieb presents himself with grace and humility. Five minutes into our conversation, Gottlieb asks, "Am I rambling?"

It took BIOTECHNOLOGY HEALTHCARE about seven weeks to catch up with Gottlieb, and we think it was worth the chase. In a wide-ranging interview with senior contributing writer Michael D. Dalzell, Gottlieb shares his thoughts on healthcare reform and its effects on health policy, biologics, and managed care.

BH: Under the individual mandate, access to affordable coverage is defined as no more than 8 percent of one's income. Does that, in essence, put the government in the business of setting healthcare premiums?

Scott Gottlieb, MD: The government *is* in the business of setting premiums, if not through political jawboning, then eventually through regulation. The health plans offered

through the healthcare exchanges are going to be very tightly regulated. They will have a minimum benefit package set by the government. So, their expenses and their income will be regulated by controls on the premiums they can charge.

When you control the ability to raise premiums and the subsidy they will receive from the federal government, and when you mandate the benefits, the only way health plans will be able to move their margins is by cheapening the product. This is going to have a profound influence on the kind of insurance that is offered.

BH: What will be the trickle-down effect of that on innovation in healthcare delivery?

A: The first question to ask is whether you believe the exchanges will become the dominant market in which healthcare benefits will be offered. I believe they will. All of the individual market and much of the small-group market will move into the exchanges. A lot of the large-group market will also move in — especially large employers that have many low-wage employees whose subsidy for buying health insurance through the exchanges will be a better deal than if they use their pretax dollars to buy insurance at work.

If you accept my premise that much of the market is going to move into these exchanges, then the insurance products sold in them will become commoditized because of the way they will be regulated. To compete, these plans will have to lower the cost of their products by tightly controlling the delivery of healthcare and paying less for services. The only way you can do that is by either having a very narrow network of physicians or by owning the physicians outright. We've seen both happening in the marketplace.

Ironically, many middle- or lower-income families who have good jobs or union benefits are suddenly going to get healthcare that's less attractive. The president pushed for healthcare reform as a way to help low-income families, but I think some families who currently get healthcare that's better than their income bracket — by that I mean people who, if they weren't getting benefits through their employer, probably wouldn't be able to afford those benefits — are going to see their benefits more closely match their income and will find themselves worse off.

Keep in mind that health insurance reform explicitly caps the medical-loss ratio. The cap is set pretty low by industry standards. If you're a new plan launching into a market where there are higher start-up expenses, or if you are a smaller plan or a specialty plan, you can't operate at that margin. I've had discussions with folks in the administration about the economic and business dynamics, and they weren't even aware of it — they didn't dismiss it, they just weren't aware of it. For example, it had never been brought to their attention that when a new health plan launches, its medical-loss ratio is usually about 70 percent, not 85 percent, because it spends so much on the launch. So, I don't think you're going to see a lot of competition.

BH: That doesn't leave much room for smaller plans that try to differentiate themselves through innovative benefit design.

A: When I was at CMS and we launched the new Part D plans, there was a focused effort on trying to get business into that market. Think back to 2003. The big criticism of Part D was that there wouldn't be enough plans — no one would want to offer one. But, lo and behold, literally thousands of drug plans entered the market, in part because the rules were created in a way to make it a good business opportunity. Over time, as these plans are repriced each year, you've seen a reversion to the mean in terms of their profitability. They've become pretty low-margin operators. There are still about 1,300 plans nationwide, but their profitability is slimmer and, frankly, prices are much lower than anticipated because of the competition.

That's in stark contrast to what's happening now — where there's a concerted effort to make sure that anyone who enters the healthcare exchanges isn't more profitable than 1, 2, or 3 percent. That's not going to get plans into that market. You're going to see a handful of established players roll up smaller players who won't be profitable, and then they will use health insurance as a low-margin way into other services that they can offer at a higher margin.

If you look at what Aetna and UnitedHealthcare have been doing, they're diversifying. They're buying medical record providers, information technology providers — companies that provide services to healthcare businesses. They'll try to run health plans in all 50 states but only with the notion of being a loss leader or a low-margin entry into other lines of business.

I'm not sure that the people who are architecting the exchanges realize that these rules are mitigating robust competition, because they still talk about these exchanges as being vibrant marketplaces where consumers will have a plethora of choices. I don't see it. You'll see 23, 30 drug plans in a state — but maybe five health plans.

BH: Is the effort to define essential benefits going to become political?
A: It already *is* political. It's going to be a big fight, because how you define essential benefits ends up determining the cost of the plans. This is an area where the people writing the regulations need to be in touch with business realities, and I'm not sure that expertise is there.

All of this scratches at a more fundamental problem: A lot of the people who wrote the Obama healthcare plan wanted a competitive framework in place, with different types of plans to be offered. I've had discussions with them, and I know they wouldn't have wanted regulation to be very tight. Those folks have now left the Obama Administration — people like Peter Orszag [director of the Office of Management and Budget], Larry Summers [director of the National Economic Council], and many others.

The folks who remain and who are writing the regulations have a much different vision. There was a philosophical divide in the administration — as there is in every administration. The folks who had a business mindset have left. In their place are people who want to be much more prescriptive.

BH: Thinking about that, and also about low margins, how might patients' access to biologics and other high-cost, high-tech healthcare interventions be affected?
A: Health plans will have to constrain the use of expensive services and find different ways to do that. It's the only way they're going to maintain profitability in an environment where their income and expenses are tightly regulated. And there will be more downward pressure on new technology by private health plans than there already is.

BH: Well, we see evidence of that in the CATT study comparing Avastin with Lucentis. Does it seem ironic that even as the government steps up enforcement against off-label promotion, here it is, trying to establish whether the off-label use of one drug is just as good as the on-label use of another?
A: By way of disclosure, I've done work with Genentech. I think this is problematic on a couple of standpoints. First, this is no way to solve the issue of getting more value for the Medicare program — taking an unusual circumstance and creating a one-off policy around it. The problems with how drugs are priced and how services are delivered are structural and long term. This is a unique circumstance and will probably never happen again, because no company will make the mistake that Genentech made in thinking that the federal government wouldn't march in and potentiate off-label use. The essential issue here is that you have a high-volume drug that you're selling at a certain price in one context, and then taking a small volume of that drug and pricing it in another context — you can't price it to the value it's delivering. Unfortunately, the government has probably disincentivized certain types of drug development with its action.

Setting that aside, should the government be involved in potentiating the off-label use of a drug? At some point, it becomes a regulatory issue in that the drug is being compounded and used in a way other than what was intended. I suspect that the FDA has avoided stepping in because of the politics — the last thing FDA wants to do is to get in the way of one or two senators' policy efforts, if you will. But I don't think the potential regulatory issues can be skirted forever.

This is not a viable strategy for deriving more value for Medicare. If this is what we're stuck with in terms of policy initiatives coming out of Washington, then we're not tackling the underlying issues.

BH: Third-party payers have been watching this study closely. One of the reasons may be that it speaks to their ongoing inability to properly evaluate and manage biologics.
A: I testified yesterday [July 21] before the U.S. Senate Special Committee on Aging. Jon[athan] Blum, director of the Center for Medicare Management, testified before me. Accept for a moment that the world of small molecules has become highly competitive under Part D — we have almost 80 percent generic drug utilization and almost 4 percent inflation in the drug program — we're getting a lot of value for Medicare beneficiaries. Could we get to 82 percent generic utilization? Maybe. Is that going to make a big difference? Could we get to 3 percent inflation? I think we're starting to get to the point where it's hard to get more incremental value.

If you look at Part B, where, by his own testimony, Jon Blum says more of the cost growth is, 13 drugs account for 50 percent of Part B costs. Those are mostly oncology agents, and most of them are highly innovative drugs that deliver a lot of value in their primary indications. So, I don't see an easy way for Medicare to take that on — they're certainly not going to deny those drugs to cancer patients. Do they take on the pricing of those products? Many of those products are priced high because they represent truly breakthrough therapies. You want a pricing scheme that rewards high value and innovation.

The advent of follow-on biologics

will create more competition. One of the things I talked about in my [July 21] testimony was allowing the medical benefit to be managed like a drug benefit. That would create more competition, and a lot of private plans are already doing it. There are ways to create a more competitive environment for injectables without controlling their price — which is the instinct — or controlling their utilization — which, politically, is going to be a very difficult lift.

BH: Have the biopharma companies done enough to communicate the value proposition of their products to payers?

A: They are doing more to communicate the value of their products. Every time a biopharma company invests in a product, it invests in research to demonstrate the value to patients. Where they are having difficulty is in communicating with patients. From a business standpoint, it's more important to make sure that patients understand the value of these products. Ultimately, whether we get bad policy will be determined by whether patients allow it. If patients aren't fully aware of the benefits that could be curtailed through bad policy, it will be easier for Washington to implement policies that restrict access to these products.

BH: What are the ups and downs of a parallel review process involving the FDA and CMS?

A: The process isn't clearly defined, and Janet Woodcock [director, Center for Drug Evaluation and Research] has said explicitly it doesn't apply to drugs. I think there are variable degrees of enthusiasm for this at FDA. It's a construct that came more from policymakers than from the career staff. FDA looks at prospective randomized studies, and CMS often looks at less rigorous types of data. So, on the drug side, aligning the data doesn't make much sense. But on the device side, where FDA will require postmarket registries as a condition of approval and where CMS may require them as a condition of coverage, it makes sense for the agencies to talk to each other.

BH: Third-party payers have hesitated to cover some molecular diagnostics because of the lack of a drug-style FDA approval process. You've warned that increased regulation of molecular diagnostic tests could stifle their development. Is there a middle ground?

A: Payers are paying for them through code stacks and fees for running the test. They don't know what they are paying for because of the way the tests are coded. Payers could solve that problem on their own, but they're waiting for CMS to solve it for them.

The problem test makers have is that it's hard for them to get premium pricing. If a test delivers more value than what the code stack yields and you want to charge a premium, that's hard to do. You have to get payers to agree to the price, or you have to get a Medicare coverage decision. Test makers need to figure out a way to make pricing commensurate with the value they're delivering, and the only way they can make that case convincingly is when the test obviates other expenses. That's what you've seen with the Oncotype DX assay, and payers have agreed to pay for it. It's reliable and helps to prevent the utilization of services that could be detrimental to a patient and cost a lot of money without delivering any benefit. I think there will be a way for those kinds of tests to get premium reimbursement.

BH: How could payers solve the reimbursement problem?

A: If they're going to reimburse for a diagnostic test, they could demand a supplementary filing, or they could create their own code structure. They all piggyback off Medicare codes and say it's too administratively difficult and expensive to require any kind of explanation of what's being charged. They complain about not knowing what they are paying for, yet they have deemed it cheaper not to know than to implement systems that would allow them to know. So then, from my standpoint, don't complain about it.

BH: Under the new healthcare system coming in 2014…

A: …Well, I'm not sure it's going to come in 2014.

BH: Well, if and when it comes, given the low margins health plans must maintain, will there be a place for premium-priced molecular tests?

A: The new system seems to be designed in a way that will keep a lot of existing test revenue neutral. So the question is, "How will the new system affect future innovation?" I don't know because I don't have enough detail about the new coding system — it's being kept very quiet, although it could have a profound impact on the healthcare marketplace, providers, and patients. A small group of stakeholders is developing this in secret, literally — you have to sign a pledge not to disclose anything when you go to one of their meetings. There is something inherently wrong with that.

The fact that this is allowed to happen is just another symptom of all the problems that plague our government's financing of healthcare.

BH: Thank you.

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